

Message

From: Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
Sent: 10/11/2017 7:38:21 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: RE: ASAP - For approval -- Press Q Due ASAP Oxitec

Thanks! Me too :)

From: Beck, Nancy
Sent: Wednesday, October 11, 2017 3:32 PM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Subject: RE: ASAP - For approval -- Press Q Due ASAP Oxitec

Good edits—thank you for jumping in!!
I'm so glad you are in OCSPP!!

Nancy B. Beck, Ph.D., DABT
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From: Bertrand, Charlotte
Sent: Wednesday, October 11, 2017 2:45 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: RE: ASAP - For approval -- Press Q Due ASAP Oxitec

Thanks Linda – couple of thoughts. Cc'd Rick so he could see my suggestions.

From: Strauss, Linda
Sent: Wednesday, October 11, 2017 2:25 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: ASAP - For approval -- Press Q Due ASAP Oxitec
Importance: High

This is late. Reporter is pining. Rick just approved. I have highlighted the timeframes in yellow.

1. Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?

Ex. 5 - Deliberative Process

Background:

Ex. 5 - Deliberative Process

2. **Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?**

Yes. These products will now be regulated under FIFRA; thus the company must show EPA that their product meets FIFRA established safety standards.

3. **If so, what is the timeline and basic structure of that sort of process?**

Ex. 5 - Deliberative Process

Background:

Ex. 5 - Deliberative Process

4. **Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?**

When If Oxitec applies for a registration, they may submit information generated in another country which may or may not be used by the EPA in its evaluation of the Oxitec mosquito product under FIFRA.

5. **Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?**

Ex. 5 - Deliberative Process

More information on these trials can be found at:

- www.epa.gov/pesticides/epa-grants-extension-experimental-use-permit-wolbachia-mosquito
www.regulations.gov/docket?D=EPA-HQ-OPP-2017-0392

From: StClair, Christie

Sent: Friday, October 06, 2017 2:08 PM

To: Hanley, Mary <Hanley.Mary@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>

Cc: Strauss, Linda <Strauss.Linda@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>

Subject: The Scientist (DDL COB today): Mosquitos

Hi Mary and Cheryl,

Is there any possibility of answering these today?

Thanks,
Christie

Abby Olena
The Scientist
Deadline is 5pm Monday, so essentially COB today.

1. Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?
2. Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?
3. If so, what is the timeline and basic structure of that sort of process?
4. Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?
5. Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?